

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST
VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO PLAINTIFFS: Joy Essman Case No. 2:12-cv-00277 Christine Wiltgen Case No. 2:12-cv-01216 Shirley Walker Case No. 2:12-cv-00873 Julie Wroble 2:12-cv-00883 Nancy Jo Williams Case No. 2:12-cv-00511	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' REPLY TO DEFENDANT'S MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE
GENERAL OPINION TESTIMONY OF DR. GREGORY T. BALES, M.D.**

I. INTRODUCTION

Plaintiffs submit this reply to Defendant's Memorandum in Opposition to Plaintiffs' Motion to Exclude the General Causation Testimony of Dr. Gregory T. Bales, M.D. ("Dr. Bales"). For the reasons set forth herein, Plaintiffs respectfully move that Dr. Bale's testimony be excluded or limited for all of the reasons set forth in their motion to exclude.

II. ARGUMENT

A. DR. BALES’S OPINIONS REGARDING COMPLICATION RATES OF NATIVE TISSUE REPAIRS, THE RISK OF DYSPAREUNIA IN PELVIC ORGAN PROLAPSE (“POP”) SURGREIES, AND MESH CONTRACTION ARE NOT ROOTED IN RELIABLE METHODOLOGY AND THEY SHOULD BE EXCLUDED.

Dr. Bales’s opinions with regard to complications associated with native tissue repairs, the risks of dyspareunia in POP repairs, and mesh contracture are not grounded in reliable methodology or scientific support, and they do not pass *Daubert* scrutiny. In its opposition, Defendant alleges that Plaintiffs merely challenge Dr. Bales’ conclusions rather than the methodology on which his opinions are based. Contrary to Defendant’s assertion, Plaintiffs’ challenge is focused on the methodology—or lack thereof—that Dr. Bales employed in forming his opinions. Namely, although he indicates that he performed a literature review, he failed to include scientific literature that contradicts his opinions, and he further failed to explain thoroughly his apparent rejection of the same. The fact that he failed to account for contradictory scientific findings does not go to his conclusions—but to whether his opinions are actually rooted in reliable methodology.

This Court previously stated that “an expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead ‘selectively [chooses] his support from the scientific landscape.’ ”¹ Indeed, “if the relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.”² This Court further indicated that an expert, who does not provide

¹ *Sanchez v. Boston Scientific Corp.*, No. 2:12-CV-05762, 2014 U.S.Dist.Lexis 137189, at *28-29 (S.D.W.Va. Sept. 29, 2014) (quoting *In re Rezulin Products Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005)).

² *Sanchez*, No. 2:12-CV-05762, 2014 U.S.Dist.Lexis 137189, at *28-29 (quoting *In re Rezulin Products Liab. Litig.*, 369 F.Supp.2d at 425).

“a sufficiently thorough explanation as to why he discounted certain literature[,]” can be found to have flawed methodology.³

Here, Dr. Bales not only failed to include studies that contradicted his opinions, but he also failed to adequately justify their exclusion. He admitted that he engaged in a process of “pick[ing] and choos[ing]” his reliance materials.⁴ When asked to explain his reason for excluding articles that were contrary to his opinions, he indicated that he could not cite to everything.⁵ Rather than providing a “sufficiently thorough explanation” as to why he disagreed with the studies, why he found them irrelevant, and/or why he thought they were otherwise flawed, he merely indicated that he simply could not include everything.⁶ Dr. Bales failed to explain how he was still able to form his opinions regarding the complications associated with native tissue repairs, the risks of dyspareunia in POP repairs,⁷ and mesh contracture in spite of relevant literature to the contrary.⁸

³ *Mathison v. Boston Scientific Corp.*, No. 2:13-CV-05851, 2015 U.S. Dist. Lexis 59047, at *18-20 (S.D.W. Va. May 6, 2015) (excluding Plaintiff’s expert’s opinion on Defendant’s motion because the expert failed to provide an adequate explanation for disagreeing with certain literature); *See also, Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 U.S. Dist. Lexis 58671, at *24-27 (S.D.W. Va. May 5, 2015) (same conclusion as *Mathison*); *see also, Sanchez*, No. 2:12-CV-05762, 2014 U.S. Dist. Lexis 137189, at *28-36 (same conclusion as *Mathison* and *Wilkerson*).

⁴ Deposition of Dr. Bales at 12:12-23, previously provided as Exhibit B to Plaintiffs’ Motion to Exclude the General Opinion Testimony of Dr. Gregory T. Bales, M.D. (hereafter “Exhibit B to Plaintiff’s Motion”).

⁵ *Id.* at 61:14-63:2.

⁶ *Id.*

⁷ Defendant argues the Plaintiffs engaged in a “sleight of hand” with the record in its Memorandum. Def. Br. at 6. Plaintiffs maintain that no sleight of hand was intended nor occurred. In fact, the answer that Dr. Bales provided (and Defendant asserts was intentionally omitted) was largely non-responsive to Plaintiffs’ counsel’s question and does not reveal anything that would be dispositive to the issues in this motion. *See* Exhibit B to Plaintiff’s Motion at 103:7-104:9. If anything, Plaintiffs could have used it as further support for the argument that his opinions are not grounded in reliable scientific support. He admitted that there are studies out there that look at complications resulting from mesh-based procedures, but that he wasn’t sure whether they differed from his opinion. Exhibit B to Plaintiff’s Motion at 103:7-23. He further went on to admit that he doesn’t believe there is any literature that supports his opinion that pain associated with vaginal mesh is no different than pain occurring with native tissue repairs. Exhibit B to Plaintiff’s Motion at 103:24-104:9. Finally, to the extent that anything pertinent was inadvertently omitted from Plaintiffs’ original Memorandum, this oversight was remedied by the fact that Plaintiffs provided the entire line of questioning as an exhibit to their motion. *See* Exhibit B to Plaintiff’s Motion.

⁸ Exhibit B to Plaintiff’s Motion at 61:14-63:2, 64:19-67:13, 68:18-71:21, 81:16-86:11, 88:1-90:20, 103:7-15-104:9, 108:1-16, 117:20-119:19, 122:6-10, 123:13-124:8, 134:14-138:24, 140:18-24.

These failures reveal Dr. Bales' flawed methodology of cherry-picking the medical literature in confirmation of a previously held belief, and further indicate that his opinions are not grounded in proper scientific support. Instead of performing an objective and thorough review of the pertinent literature, Dr. Bales merely cited to articles that tended to support his opinions and without reason or support largely disregarded those that tended to contradict his beliefs. Such a biased, incomplete review of the scientific medical literature does not rise to the level of reliable methodology required by *Daubert* and its progeny and, accordingly, his opinions on these topics should be excluded.⁹

B. INCONSISTENCIES IN AN EXPERT'S OPINION CAN REVEAL THAT HIS OPINIONS ARE BASED ON AN UNRELIABLE METHODOLOGY

Interestingly, Defendant cites *Sanchez* for the proposition that inconsistent statements are best addressed by cross-examination.¹⁰ However, as this Court is no doubt aware, expert testimony was excluded in *Sanchez* because of the expert's inconsistencies.¹¹ Indeed, *Sanchez* indicates that, while cross-examination is the traditional way to attack shaky evidence, expert testimony can be excluded where the expert's inconsistencies "directly shed light on the unreliability of his method."¹² The same is true, here, where Dr. Bales' inconsistencies in his report and his deposition testimony reveal that his opinions regarding the TVT-O are not grounded in reliable methodology.

⁹ See *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994) (noting that reliability was lacking where experts "formed their opinions before reading the relevant literature"); see also, *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 783 (10th Cir. 1999). "Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method." *Claar*, 29 F.3d at 502-03. "[This type of action] turns scientific analysis on its head. Instead of reasoning known facts to reach a conclusion, the expert[] here reasoned from an end result in order to hypothesize what needed to be known but what was not." *Sorensen By And Through Dunbar v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994).

¹⁰ Def. Br. at 11.

¹¹ *Sanchez*, No. 2:12-CV-05762, 2014 U.S. Dist. Lexis 137189, at *36-38 (excluding Plaintiff's expert's opinions on Defendant's motion, finding that his inconsistencies revealed an unreliable methodology).

¹² *Id.*

C. DR. BALES IS NOT QUALIFIED TO TESTIFY AS TO THE ADEQUACY OF THE WARNINGS

On the issue of whether Dr. Bales is qualified to testify as to the adequacy of the warnings, Defendants cite *Tyree* and argue that it is inapplicable to Dr. Bales' opinions regarding the warnings. In *Tyree*, this Court precluded a urologist, Dr. Green, from testifying that the warnings were adequate and found that, "without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks he has observed in his own practice."¹³ Dr. Bales does not have any additional qualifications in the realm of product warnings that Dr. Green lacked.¹⁴ In fact, Dr. Bales admitted that he is not an expert in regulatory affairs nor is he an expert in industry standards for warnings.¹⁵

Like Dr. Green in *Tyree*, Dr. Bales' opinions that the warnings were adequate are based on his clinical observation of certain risks and complications, which were warned of in the IFU.¹⁶ Because the risks he observed were in the IFU, he concludes there are no other possible risks or complications that should have been included.¹⁷ As this Court aptly recognized, there is quite a distinction between an expert opinion that the warnings lacked "a discrete risk which they have personally observed" and an expert's opinion that all possible risks were warned of, even if they have not personally observed them.¹⁸ Here, Dr. Bales's opinions fall into the latter category and they are premised on the logical fallacy that because he has not seen them, they do not exist.¹⁹ Further, Dr. Bales' opinion that risks not warned of were well-known by surgeons at the time is

¹³ *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-584 (S.D. W. Va. 2014).

¹⁴ *See id.*

¹⁵ Exhibit B to Plaintiff's Motion at 45:14-46:3.

¹⁶ *See Tyree*, 54 F. Supp. 3d at 583-584.

¹⁷ *See id.*

¹⁸ *Id.*

¹⁹ *See id.*

not supported by the relevant scientific literature. Finally, to the extent that Dr. Bales seeks to opine on matters concerning the FDA, as he does in his report,²⁰ Plaintiffs request that this testimony be excluded as he is unqualified to opine on such matters.²¹

III. CONCLUSION

For the foregoing reasons and those incorporated by reference in Plaintiff's original Memorandum, Dr. Bales' opinions should be excluded.

This 16th day of May, 2016.

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²⁰ Expert Report of Dr. Gregory T. Bales at 10-13, 21-23, previously provided as Exhibit A-1 to Plaintiff's Motion to Exclude the General Opinion Testimony of Dr. Gregory T. Bales, M.D.

²¹ See e.g. *Tyree*, 54 F. Supp. 3d at 550-551 (finding that Plaintiff's expert, a urogynecologist, was unqualified to offer opinions on matters concerning FDA compliance).

CERTIFICATE OF SERVICE

I hereby certify that on May 16th, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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